

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1461V

Filed: November 6, 2017

UNPUBLISHED

GAIL DIRKSEN,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU);
Ruling on Entitlement; Fact Hearing;
Findings of Fact; Causation-In-Fact;
Influenza (Flu) Vaccine; Shoulder
Injury Related to Vaccine
Administration (SIRVA)

Shealene Priscilla Wasserman, Muller Brazil, LLP, Dresher, PA, for petitioner.

Lara Ann Englund, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

Dorsey, Chief Special Master:

On November 4, 2016, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,² (the “Vaccine Act”). Petitioner alleges that she suffered a left shoulder injury caused by her November 7, 2013 influenza (“flu”) vaccination. Petition at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed below, the undersigned finds that petitioner is entitled to compensation.

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History Prior to Hearing

On November 4, 2017, along with her petition, petitioner filed medical records marked as exhibits 1-4. (ECF No. 1.) However, petitioner did not file a statement of completion until December 19, 2016. (ECF No. 9.) Subsequently, during the initial status conference held January 13, 2017, additional outstanding medical records were identified. (ECF No. 11.) Additional records and an amended statement of completion were filed on February 27, 2017. (ECF Nos. 12-13.)

On April 28, 2017, respondent filed his Rule 4(c) Report. (ECF No. 17.) Respondent recommended against compensation in this case. (*Id.*) Respondent argued, *inter alia*, that the evidence was insufficient to show a logical sequence of cause and effect or a temporal relationship between vaccination and injury because petitioner did not seek medical attention for her shoulder injury until nearly four months after her vaccination, the injection site was not included in her vaccination record, and she did not adequately describe to her doctors the relationship between her vaccination and her shoulder pain. (*Id.*, p. 4.)

Additional records were filed on May 23, 2017. (ECF No. 19.) Thereafter, following a status conference held by the staff attorney managing this case, the undersigned concluded that the case was ripe for a fact hearing. (ECF No. 20.) In preparation for the hearing, petitioner filed additional evidence on August 30, 2017, September 8, 2017, and September 11, 2017. (ECF Nos. 25, 27-28.)

II. Fact Hearing and Preliminary Ruling

A fact hearing was held in Washington, D.C., on September 14, 2017. (See Transcript of Proceedings (“Tr.”) at ECF No. 42.) Petitioner was the sole witness. At the conclusion of the hearing, the undersigned informed the parties that she intended to issue a preliminary ruling from the bench. (Tr. 51-52.) The parties consented. (Tr. 52.) The undersigned stated that her ruling would resolve (1) the site of administration of petitioner’s vaccination, (2) whether the onset of petitioner’s symptoms occurred within 48 hours of vaccination, and (3) whether petitioner sustained a shoulder injury related to vaccine administration (“SIRVA”). (Tr. 52-53.)

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table (“Table”). See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 82 Fed. Reg. 6294, Jan. 19, 2017; National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 82 Fed. Reg. 11321, Feb. 22, 2017 (delaying the effective date of the final rule until March 21, 2017). Although petitioner’s claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned’s findings were informed by the criteria used to evaluate such claims. (See Tr. 52-55.) The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine

injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

82 Fed. Reg. 6303 (Qualifications and Aids to Interpretation for SIRVA); see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

With these factors in mind, the undersigned made the following preliminary findings of fact:

- “Ms. Dirksen had no history of pain, inflammation, or dysfunction of her left shoulder prior to her flu vaccine administration. Her medical records do not reveal any history of prior left shoulder problems. Additionally, her testimony here today is consistent with that finding.” (Tr. 54.)
- “[B]ased on the petitioner’s affidavit, particularly with regard to her second affidavit, her testimony here today, and the history documented in the medical records, Exhibit 3 at page 11, with regard to Dr. Joshi’s entry, I find that the onset of pain was within 48 hours.” (*Id.*)
- “[B]ased upon the petitioner’s testimony and the medical records of Dr. Joshi that petitioner’s pain and reduced range of motion were limited to the left shoulder *in which the vaccine was administered.*” (Tr. 54-55 (emphasis added).)
- “[T]here is no other condition or abnormality identified by petitioner or by Dr. Joshi which would explain her symptoms.” (Tr. 55.)

The undersigned further concluded that:

“[T]he totality of the facts and circumstances set forth in the exhibits and given today in the testimony, that there is preponderant evidence of causation, specifically the petitioner presented to her chiropractor on February 5, 2014, complaining of shoulder pain -- see Exhibit 6 at page 8 - - and to Dr. Joshi on 18 April 21st, 2014 -- see Exhibit 3 at pages 8 and 11 and see also Exhibit 3 at page 1. These signs and symptoms and diagnosis include reduced range of motion, pain, and a diagnosis of adhesive capsulitis. And I find that these are causally related to her flu vaccine, proven by preponderant evidence sufficient to fulfill her obligation with regard to evidence of causation.

Tr. 55.

III. Closing of the Record Regarding Entitlement

Following the undersigned's preliminary ruling, respondent's counsel informed the undersigned of respondent's position that the record of the case lacked any expert or physician testimony regarding whether petitioner's injury was caused-in-fact by the vaccination. (Tr. 57.) In light of respondent's position, the undersigned took judicial notice of two articles pertaining to causation of vaccine-related shoulder injuries which were filed as court exhibits. These articles are: B. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Court Exhibit I, and M. Bodor and E Montalvo, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007), filed as Court Exhibit II. (ECF No. 29.) Respondent was provided 30 days to provide any additional evidence regarding entitlement or any response to the court exhibits. (*Id.*) No further filings were made and the undersigned announced the record as to entitlement closed as of October 27, 2017. (ECF No. 45.)

IV. Conclusion

A cause-in-fact injury is established when petitioner demonstrates by a preponderance of the evidence: (1) she received a vaccine set forth on the Vaccine Injury Table; (2) she received the vaccine in the United States; (3) she sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months. § 13(a)(1)(A). To satisfy the burden of proving causation in fact, petitioner must establish each of three factors announced by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.* by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

In light of all of the above, and in view of the submitted evidence, including the medical records, credible witness testimony, and findings of fact, the undersigned finds petitioner entitled to Vaccine Act compensation.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master